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RANKIN, HILL, PORTER & CLARK, LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405			EXAMINER DRODGE, JOSEPH W	
			ART UNIT	PAPER NUMBER

1723

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/691,113  
Filing Date: October 22, 2003  
Appellant(s): SHEKUNOV ET AL.

**MAILED**  
MAY 12 2006  
**GROUP 1700**

Randolph E. Diggs, III  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed July 28, 2005.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

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The brief contains a statement that there are no related appeals or interferences.

**(3) Status of Claims**

The statement of the status of the claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal in the brief is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

## (9) GROUNDS OF REJECTION OF RECORD

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-19 and 21-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al PGPUBS Document US2004/0091546, of record.

Johnson et al disclose providing a 1<sup>st</sup> solution with dissolved solute (paragraphs 34 and 36), providing an antisolvent that may be supercritical carbon dioxide (paragraphs 58 and 63), flowing the fluids through a chamber or vessel containing a rotor to mix (paragraph 41) and mixing in the annular space between rotor and vessel wall to collect precipitated particles (paragraph 41 and 58).

For claims 3,7-11,20,21,23-29, plural solvents may be added through additional, multiple inlets and ports at varied locations (paragraph 37 and 45). For claim 9, co-axial ports are disclosed at paragraph 45 concerning inlet tubes directed towards each other.

For claims 2 and 22, paragraph 41 concerns streams forced to vessel walls by centripetal forces.

For claims 4,5 and 24-26, ultra-fast mixers and mm mixer dimensions are shown at paragraph 35,37 and 38.

For claims 12,16,30 and 34 varied solutes are at paragraph 21 and 66.

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For claims 14,15,32 and 33, see paragraph 20 and 64 regarding emulsions and suspensions.

For claims 16, 21 (and claims dependent therefrom), forming coated cores is disclosed at paragraphs 19, 45 and 57.

For claims 17 and 35, paragraph 68 discusses nm size particles.

For claims 18 and 36, paragraph 40 and 49 concerns rotor process control features.

For claims 19 and 37, entire disclosure is devoted to particle formation.

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## NEW GROUNDS OF REJECTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al PG PUBS Document US2004/0091546 in view of Holl et al, also of record.

Claim 6 differs from Johnson et al in requiring the inner wall of the chamber to be spaced from the surface of the rotor a distance of about 0.1 mm to about 2.5 mm, although Johnson et al disclose mixing chambers having dimensions in the single mm range in paragraphs 37-38. Holl et al, of record, teach rotor-stator mixing chambers for mixing processes for materials including solutions, emulsions and suspensions (column 1, lines 7-19 and column 7, lines 45-52). Holl et al teach spacing between rotors and stator chamber walls of distances not exceeding about 1.5 mm (column 5, lines 7-28) or not exceeding about 1.7 mm (column 4, lines 12-41), thus meeting the spacing limitation of claim 6. It would have been obvious to one of ordinary skill in the art to have utilized a rotor stator mixer, in the Johnson et al process, having a spacing between rotor and stator chamber wall of about 0.1 mm to about 2.5 mm, as taught by Holl et al, in order to avoid introducing Taylor vortices and thus facilitate a more complete, uniform mixing of the introduced solutions.

#### (10) RESPONSE TO ARGUMENTS

It is argued, with respect to claim 1, that Johnson et al does not disclose flow of process solvent and non-process solvent through a mixing vessel/chamber as required. It is submitted that Johnson et al disclose flow of solvent into and out of mixing chambers from inlets to outlets at paragraphs 41,45 and 47 and illustrated in Figure 1.

It is argued, with respect to claim 1, that Johnson et al does not disclose mixing of supercritical carbon dioxide with solvents during the mixing process to form particles, instead only using supercritical fluid during a process step occurring after mixing and particle formation. It is submitted that paragraph 58 discloses introduction of carbon dioxide into the mixing chamber/vessel at elevated temperatures and pressures, and possibly as a liquid state of matter and that paragraph 63, states that supercritical fluid may be utilized either during or after the nanoparticle formation, or mixing, process.

It is argued, with respect to claim 1, that Johnson et al does not disclose introduction of solution and supercritical carbon dioxide into the annular space between rotor and chamber wall. It is submitted that paragraph 41 discloses introduction of process streams into rotor-stator mixers, and states that the streams of solvent being mixed are forced by centripetal forces towards the walls of the mixing chamber/vessel, which would be the annular space between rotor and chamber wall in the case of a rotor stator mixer being the mixing chamber/vessel employed.



It is argued, with respect to claim 6, that Johnson et al does not teach the inner wall of the chamber spaced from the rotor by a distance of about 0.1 mm to about 2.5 mm. It is submitted that Johnson et al firstly disclose in paragraphs 37 and 38, chamber dimensions, including diameters that may be as small as 1.25 mm. It is also submitted that Holl et al teach spacing between rotors and stator chamber walls of distances not exceeding about 1.5 mm (column 5, lines 7-28) or not exceeding about 1.7 mm (column 4, lines 12-41) for mixing of materials including solutions, emulsions and suspensions (column 1, lines 7-19 and column 7, lines 45-52), for the express purposes of avoiding formation of Taylor vortices or other turbulence that would prevent complete and uniform mixing of the materials.

It is argued, with respect to claim 9, that Johnson et al does not disclose coaxial ports for introducing respective solvent streams. It is submitted that paragraph 45 of Johnson et al disclose that inlet ports may be arranged to direct streams towards each other so that they may collide.

It is argued, with respect to claim 14, that Johnson et al does not teach or suggest that the first solution being mixed comprises an emulsion. It is submitted that in paragraph 64 of Johnson et al, addition of emulsifiers to the process or non-process solvent streams in the form of supplemental additives, which would convert such solvent stream(s) to emulsions.

It is argued with respect to claim 21, that the further limitation, beyond those of claim 1, requiring formation of precipitated particles having a core structure comprising the first solute comprised in the first solution and shell structure containing the second solute comprised in the second solution, is not disclosed, taught or suggested by Johnson et al. It is submitted that paragraphs 19, 45 and 57 of Johnson et al are directed to such teaching. In paragraph 19, it is stated that additive target molecules contained in a solvent can be encapsulated (i.e. formed with a shell) and stabilized when co-precipitated with an amphiphilic copolymer. In paragraph 45, it is stated that the additive target molecule and amphiphilic copolymer can be introduced into the mixing vessel via different solvent streams and via different inlet tubes. In paragraph 57, last sentence, it is stated that amphiphilic copolymer can be used to coat hydrophobic target molecules.

(11) ***Related Proceedings Appendix***

There are no related proceedings.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted

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May 5, 2006

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November 9, 2004